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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,339	03/29/2001	Sara Fuchs	FUCHS=2A	3100

1444 7590 06/08/2005

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,339	FUCHS ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,12,14-19,25,27,28 and 30-41* is/are pending in the application.

4a) Of the above claim(s) ___ is/are withdrawn from consideration.

5)☒ Claim(s) *12* is/are allowed.

6)☒ Claim(s) *8,9,16-19,28,30 and 32-39* is/are rejected.

7)☒ Claim(s) *14,15,25,27,31,40 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 1/24/05 has been entered.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately in the* "**Sequence listing**" *and in the text of the description* and *claims whenever described.* In particular, SEQ ID NO: 2 is not the same as that disclosed in Figure 1 at Ala 33, which alternatively is Val33, and therefore, is either a typographical error or constitutes possible new matter. In other words, the disclosure on page 15 and Figure 1 is inconsistent with Applicants' arguments on page 17 of the response. Appropriate correction is required.

Note that a new Sequence Listing, CRF and the appropriate statements related to no new matter is requried, as indicated in the attached.

Note further that failure to respond to both the requirements for sequence compliance and this final office action below will be held as *nonresponsive*, and may result in *abandonment* of this application. See MPEP 2422 & 2431.

3. The rejection of claims 8-9, 14-19, 27 & 30-31 under 35 U.S.C. 112, first paragraph for new matter is withdrawn due to the amendment of the claims.

4. The rejection of claims 8-9, 16-19, 25, 27-28 & 30-31 under 35 U.S.C. 112, first paragraph for lack of written description is withdrawn due to the amendment of the claims.

5. The rejections of claims 8, 9 & 9(vi) under 35 U.S.C. 112, second paragraph, as being indefinite are withdrawn due to the amendment of the claims.

6. The rejection of claims 15 & 31 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims and Applicants' arguments.

7. The rejection of claims 9 & 25 under 35 U.S.C. 102(b) as being anticipated by Talib et al is withdrawn due to the amendment of the claims or due to further consideration by the Examiner.

8. Applicants' arguments filed 1/24/05 have been considered but are not found persuasive.

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 25, 27, 28, 32, 36 & 40 are objected to because of the following informalities: "toleragen" is misspelled in claims 25, 27, 28, 32, 36 & 40. Appropriate correction is required.

11. Claim 12 is allowed.

12. Claims 14, 15, 25, 27, 31 & 40-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

It is also suggested that claim 32 (iii) be amended to " a polypeptide Hα1-210 consisting of the amino acid residues of SEQ ID NO: 2" to reflect more conventional claim language.

13. Claim 19 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because the new recitation of "a fusion polypeptide" still lacks proper antecedent basis in the majority of the recited Markush group in base claim 8, in which again only base claim 8(v) recites the limitation of a "fused polypeptide"; thereby, still confusing what metes and bounds are encompassed by this recitation. For example, are additional fusion polypeptides now being claimed, besides that recited in claim 8(v)?

14. Claims 8, 16-19, 30 & 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how a "binding assay to α-bungarotoxin", which recites no process steps, is envisioned to determine whether or not "the native conformation" is obtained; thereby, being also incomplete.

It is suggested that amending the claims to "as determined from a binding assay to α-bungarotoxin, where weaker binding to α-bungarotoxin when compared to the corresponding fragment from the acetylcholine receptor (AChR) α-subunit extracellular domain indicates said fused polypeptide has not assumed the native conformation of the α-subunit of AChR" should obviate this rejection. For example, see page 28 of the specification.

15. Claims 8, 9, 16-19, 30 & 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoepfer et al. (1988), for the reasons made of record in Paper No: 11 (mailed 1/30/03), 14 (mailed 10/14/04) & 20040721, and as follows.

In contrast to Applicants' arguments on page 16 of the response, the recitation of "fused to an additional polypeptide at its N- and/or C-terminal end" to "amino acid residues 122-210 of SEQ ID NO: 2" in claims 8(v), 9(iv) & 36 are still met by the teachings of Schoepfer et al. whether or not a.a. residue #33 is Ala, versus Val, in SEQ ID NO: 2, as argued by Applicants on page 17 of the response (i.e., especially as it relates to claim 9(iv)). It is noted that nucleotide position # 283 of SEQ ID NO: 1 is different from Schoepfer's nucleic acid. Note further that pages 20 & 26 of the specification indicates that the AchR α-subunit *extracellular* domain polypeptide itself (i.e., a.a. residue #s 1-210, or fragments thereof) function as a tolerogen. *In arguendo*, the putative a.a. change in Schoepfer at a.a. position #33, as currently recited in SEQ

ID NO: 2, changes the native conformation of the α-subunit of the human acetylcholine receptor, absent evidence to the contrary; thereby, still anticipating the current claims, as recited.

16. Claims 8, 9, 16-19, 28, 30 & 32-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Talib et al. (1991; IDS Ref #AM), for the reasons made of record in Paper NOs: 11 (mailed 1/30/03), 14 (mailed 10/14/04) & 20040721, and as follows.

In contrast to Applicants' arguments on page 16 of the response, the recitation of "fused to an additional polypeptide at its N- and/or C-terminal end" to "amino acid residues 122-210 of SEQ ID NO: 2" in claims 8(v), 9(iv) & 36 are still met by the teachings of Talib et al. *In arguendo,* the sole difference between Talib's sequence and DNA encoding Hα1-210 of claims 8(iv) & (v), 9(iv), 28, 30, 32 & 36 is the mere addition/fusion of the Met start codon residue at the N-terminal end of SEQ ID NO: 2, as indicated in Figure 1 (i.e., assuming SEQ ID NO: 2 contains a typographical error, based on Figure 1 being the sole amino acid sequence disclosed in the specification), which is then inherently removed during proteolytic processing of eukaryotic proteins, and therefore, then "cod[es] for a polypeptide toleragen (*sic*)... consisting of amino acid residues [1-210] of SEQ ID NO: 2". This fusion polypeptide of Talib also inherently "does not assume the native conformation of the α subunit of the human acetylcholine receptor" because Talib's polypeptide constitutes a truncated version of the human acetylcholine receptor which is the extracellular domain of this receptor subunit. Note, pages 20 & 26 of the specification disclose that the AChR α-subunit *extracellular* domain polypeptide itself functions as a tolerogen.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
June 1, 2005

ROBERT C. HAYES, Ph.D.
PATENT EXAMINER

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Application No.: 09/820,339

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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